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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,625	Applicant(s) COOK ET AL.	
	Examiner Tuan V. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/24/04, 9/29/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 2 and 17 are objected to because of the following informalities: both claims recite limitation "the length". There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.
2. Claims 3 and 18 are objected to because of the following informalities: both claims recite limitation "the width". There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 4-13, 15-16, and 19-20 is rejected under 35 U.S.C. 102(b) as being anticipated by Pedlick et al. (U.S. 6,270,518).**
5. Referring to claims 1, 4-13, 15-16, and 19-20, Pedlick discloses (see Figs. 35-36 and 38-41) a bioabsorbable suture anchor 301 for anchoring tissue to a bone,

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comprising: an elongate body 310 defined by a longitudinal axis; a first, leading end 302, includes a rounded distal end 304, and a second, trailing end 306; the elongate body comprising two opposed surfaces 320 between the first and second ends, and a plurality of sidewalls 312, 316 extending between the two opposed surfaces; a flared portion 308, includes biting edge 322 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 330, that includes rounded edge 330 on both sides, formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 41); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the suture; and the anchor also includes a blind hole 334 for engaging with insertion tool (see Fig. 36), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 14, lines 1–60). Pedlick also discloses the method of deployment the anchor into a bone hole as claimed in claims 19-20 (see col. 18, line 53 to col. 19, line 55).

6. **Claims 1, 4-13, 15-16, and 19-20 is rejected under 35 U.S.C. 102(e) as being anticipated by Donnelly et al. (U.S. 6,773,436).**
7. Referring to claims 1, 4-13, 15-16, and 19-20, Donnelly discloses (see Figs. 1-2C, 4a-4b and 9A-9D) a bioabsorbable suture anchor 10 for anchoring tissue to a

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bone, comprising: an elongate body 12 defined by a longitudinal axis L; a first, leading end 14, includes a rounded distal end, and a second, trailing end 16; the elongate body comprising two opposed surfaces 12 between the first and second ends, and a plurality of sidewalls 20, extending between the two opposed surfaces; a flared portion, includes biting edge 22 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 24, that includes rounded edge 28 on both sides, formed in the elongate body for passage of a suture strand 2 (see Fig. 2a) therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 4a and 4b); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the suture; and the anchor also includes a blind hole 30 for engaging with insertion tool 400 (see Fig. 9), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 3, line 43 to col. 4, line 65). Donnelly also discloses the method of deployment the anchor into a bone hole as claimed in claims 19-20 (see col. 8, lines 17-65 and claims 19-20). Donnelly discloses insertion tool 400, however, Donnelly silent with respect to the insertion tool having a handle. Here it is noted that the insertion tool for deployment of a suture anchor having a handle is old and well known in the art, thus Donnelly inherently discloses the insertion tool having a handle.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. **Claims 2, 3, 14, 17, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pedlick et al.**
11. Referring to **claims 2, 3, 17, and 18**, Pedlick discloses the size of suture anchor is 3 mm (see col. 9, line 24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width is in the range of about 1-3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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12. Referring to **claim 14**, Pedlick discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer (see col. 10, lines 45-60). It is old and well known in the art that polymer, Nitinol, stainless steel has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (if the material is stainless steel) for the indication of the location of the anchor in the surgical site. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use blue dye because Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Pedlick device, and applicant's invention, to perform equally well.
13. **Claims 2, 3, 14, 17, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Donnelly et al.**
14. Referring to **claims 2, 3, 17, and 18**, Donnelly discloses the diameter size of suture anchor is 3 mm and the suture anchor having an overall size smaller than conventional bone anchors (see col. 4, lines 35-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is in the range about 1-3 mm, since it has been held that

where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Referring to **claim 14**, Donnelly discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer (see col. 4, lines 62-68 and col. 6, lines 26-32). It is old and well known in the art that polymer and Titanium has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (if the material is Titanium) for the indication of the location of the anchor in the surgical site. Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use blue dye because Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Donnelly device, and applicant's invention, to perform equally well.
16. Bartlet, U.S. 5,626,612, discloses suture anchor having the length of elongate body is in the range of 1-12 mm and the width or largest diameter of the anchor (see entire document).

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
August 13, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
